

107TH CONGRESS  
1ST SESSION

# H. R. 386

To amend the Federal Food, Drug, and Cosmetic Act with respect to orphan drugs.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 2001

Mr. THORNBERRY introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to orphan drugs.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Orphan Drug Program  
5       Improvement Act of 2001”.

6       **SEC. 2. FEDERAL FOOD, DRUG, AND COSMETIC ACT;**

7                       **AMENDMENTS TO PROGRAM FOR ORPHAN**

8                       **DRUGS.**

9       (a) CONFORMING ORPHAN-DRUG DESIGNATION TO  
10       REFLECT LABELING OF APPROVED DRUG.—Section

1 526(a) of the Federal Food, Drug and Cosmetic Act (21  
2 U.S.C. 360bb(a)) is amended—

3 (1) by redesignating paragraph (2) as para-  
4 graph (3); and

5 (2) by inserting after paragraph (1) the fol-  
6 lowing paragraph:

7 “(2) In approving an application filed pursuant to  
8 section 505 for a drug designated under paragraph (1),  
9 or approving the issuance of a license under section 351  
10 of the Public Health Service Act for a drug so designated,  
11 the Secretary shall, with respect to the intended use of  
12 the drug, conform the designation of the drug under para-  
13 graph (1) to reflect the labeling that is approved for the  
14 drug.”.

15 (b) CLINICAL SUPERIORITY OF SUBSEQUENT  
16 DRUG.—Section 527 of the Federal Food, Drug and Cos-  
17 metic Act (21 U.S.C. 360cc) is amended—

18 (1) in subsection (a), by striking “subsection  
19 (b)” and inserting “subsections (b) and (c)”; and

20 (2) by adding at the end the following:

21 “(c)(1) In a case in which the Secretary approves an  
22 application filed pursuant to section 505, or issues a li-  
23 cense under section 351 of the Public Health Service Act,  
24 for a drug designated under section 526 for a rare disease  
25 or condition, and such drug is approved or licensed be-

1 cause it is considered to be clinically superior to a pre-  
2 viously approved or licensed drug designated under section  
3 526, the seven-year period of prohibition against approval  
4 described in subsection (a) shall apply only to prohibit ap-  
5 proval of drugs that exhibit the same clinically superior  
6 features.

7       “(2) In paragraph (1), the term ‘clinically superior’  
8 means a drug (that is otherwise the same drug) that is  
9 shown to provide better safety or better efficacy, or to pro-  
10 vide a major contribution to patient care.

11       “(3) In making a determination of whether a drug  
12 is clinically superior for purposes of this subsection, the  
13 Secretary, upon request of the applicant involved, shall  
14 refer a determination as to whether the drug provides a  
15 major contribution to patient care to an advisory com-  
16 mittee.”.

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